

PROCEDURE FOR OBTAINING A RETAIL WATER FACILITY LICENSE

License Application Form: DHS 8602

California Health and Safety Code (H&SC) Section 111120 requires that a retail water facility (RWF) operator in California obtain a license issued by the Department of Health Services' Food and Drug Branch (FDB) to operate a RWF. The following describes what you must do to obtain your license.

LICENSE APPLICATION

Submit a fully completed application form with the required fee. You may call the FDB Water Licensing Desk at (916) 650-6515 to receive **Form DHS 8602** by mail, or download the form from the FDB website (<http://www.dhs.ca.gov/fdb/>; "Application Instructions and Forms").

Please write your firm name (If your check does not bear the firm name), license number (If the application is for renewal of your license), and the phrase "PCA Code 85125" on your check or money order. The fee is non-refundable.

The license is valid for one calendar year and expires on December 31. The business address must be that of the retail water facility, not that of the corporate headquarters. The mailing address can be either that of the facility, corporate headquarters or the firm's branch office (the license will be mailed to the mailing address). Any incomplete and/or illegible applications will be RETURNED to the applicant. [NOTE: A change of the RWF ownership will invalidate a RWF license. The new owner of a licensed RWF must apply for a NEW license (cannot simply renew the license). Neither cleaning/sanitation of water bottles nor bottling of water is allowed at a licensed RWF.]

Water Source:

- a. If you intend to use public drinking water as the source, you must indicate the name, address and phone number of the public (municipal) Water District on the application form. You are not required to analyze the source water, but must obtain a copy of the Water District's most recent chemical, physical, radiological and microbiological analysis data for the water.
- b. If you intend to use a private well or a spring as the source, you must indicate the name, address, phone number, and license number of the private water source on the application form (Only water from a licensed private water source can be used for further treatment at your facility). You are not required to analyze the source water, but must obtain a copy of the water quality analysis data from the private water source. Note: A well or a spring owned by RWF, regardless of whether it is located on the same premise or not, cannot be used as a source unless it has already been licensed as a private water source by FDB.

INSPECTION

FDB will perform an on-site inspection of your facility to assure that the facility meets the requirements specified in state and federal laws. Please contact one of the closest FDB offices (see the last page of this Procedure) for an appointment for inspection.

NOTE: *Submit the information specified below (items 1 and 4) in duplicate to a Food and Drug Investigator at the time of inspection of your facility.*

1. Water Quality Analysis:

- a. Source water quality: Submit a copy of source water quality analysis [Note: RWF can obtain a copy of the source water analysis data from the relevant Water District if it is public (municipal) drinking water; or the relevant private water source if the water is from a licensed private well or a spring].
- b. Product quality:
 - 1) Request the testing laboratory* of your choice to take water samples at your store and perform the analyses shown below. At least four random sub-samples of water must be taken from the dispenser during the operation hours of the day (For the first sub-sample, run the water for at least 1 minute before taking it). The laboratory makes one composite of the four sub-samples for analysis.
 - (i) bacteriological quality (total coliforms),
 - (ii) lead,
 - (iii) Volatile organic chemicals [Note: VOCs must be determined by the U.S. EPA Method 524.2. (Revision 4.0), and you must submit data for all the chemicals detected by the test method].

[Note: Pursuant to H&SC Section 111155, FDB may ask you to test for any contaminant(s) if FDB suspects the substance(s) may be present in the water.]

* Testing Laboratories: All testing must be done by a California certified water laboratory [Please contact the California Environmental Laboratory Accreditation Program at (510) 540-2800 for the list of locations/phone numbers of the certified laboratories] or by a laboratory certified by the United States Environmental Protection Agency (USEPA). Testing done by a laboratory approved by the primary enforcement authority in states which have been

granted primacy by the USEPA is also acceptable according to H&SC 111165.

- 2) Submit a copy of the analyses.

2. Operation:

- a. A schematic diagram of the water treatment process at your facility (please describe in detail).
- b. Equipment and materials: Only process equipment and materials that have been approved for food or potable water use can be utilized in your facility. Submit copies of the specification sheet for each piece of equipment and material** (please do not send copies of promotional materials or advertisement). On the front page of each copy, indicate whether the equipment or material was approved for food or potable water use, and highlight the relevant information in the specification sheet or attach such information to the copies.

** You must submit copies of specification sheets for the following equipment and materials:

- 1) Pipes, hoses, fittings, water faucets (if specification sheets are not available, indicate the schedule #, other relevant information, and the name of the approval organization).
- 2) Pipe cement or bonding agent (if spec sheets are not available, indicate whether it was approved for use in food contact surfaces, and the name of the approval organization).
- 3) Water softener (if applicable: type of resins).
- 4) Carbon filter (if applicable).
- 5) Particle or polishing filter (if applicable).
- 6) Reverse osmosis (if applicable: also components such as RO membranes, RO pump).
- 7) Deionization (if applicable).
- 8) Storage tank (also indicate whether vented or not).
- 9) Pump (also indicate whether materials used for making the pump have been approved for food or potable water contact surfaces and the name of the approval organization; Is it water-lubricated?).
- 10) Re-pressurization tank (if applicable).
- 11) Post carbon filter (if applicable).
- 12) Ultraviolet lights (UV) for disinfection (if applicable) (the UV equipment must have a minimum UV dosage of 16,000 uW sec/cm²).

- 13) Ozonator (if applicable): The ozone generator must have enough capacity for providing water with more than 0.1 ppm ozone for at least 5 minutes.

Note: If you are unable to submit the evidence that the process equipment and materials have been approved for food or potable water use, you will be required to perform the full water analysis as specified by H&SC Section 111080.

3. Equipment maintenance and Record Keeping (Note: the records must be kept for at least two years):
 - a. Copy of the equipment maintenance schedule.
 - b. Copy of the process control and daily monitoring procedures (also include a copy of the daily activity log, and the log for coliform testing/test results).
 - c. Written procedures for cleaning and sanitizing of equipment. Identify the specific brand names of the cleaning and sanitizing compounds (if available, chemical names) and concentrations to be used. Indicate whether they have been approved for food contact surfaces. Identify the approving or certifying organization.
4. Submit all labels, advertising, and promotional materials (original; not photocopies). They must be in compliance with H&SC Section 109875 et seq. and applicable regulations.

If a product designation other than “drinking water” (e.g., "purified" "spring", "mineral") is used on the label or labeling, the water must meet the definition for the terms as specified in H&SC Section 111175 and 21 CFR 165.110(a)(vi).

5. After obtaining the license, you must do the following:
 - a. Coliform analysis: You must test water for total coliforms at least once every six months. Maintain the original test result report, and send a photocopy of the report to your local FDB. The testing laboratory may send a copy of the test report directly to the local FDB office on your behalf. The laboratory must clearly identify your firm name, address, and license number on the report. You can obtain the list of certified laboratories near your location by calling DHS' Environmental Laboratory Accreditation Program (ELAP) at (510) 540-2800 or by visiting the following ELAP website: <http://www.dhs.ca.gov/ps/ls/elap/html/LablistStart.htm>.

Collect four samples, and send all four samples to the testing laboratory (the testing laboratory may sample directly, or ask you to take the samples following its

instruction for sample collection). The laboratory will randomly select one of the four samples and test for coliforms.

The laboratory can use the presence/absence (P&A) test for the coliform analysis. Only negative (absence) test data are acceptable. If a sample tests positive (presence), you must resample the water (i.e., four random samples) within 24 hours and test using the multiple tube-fermentation method. If the test data show that the water contains more than 2.2 most probable numbers (MPN)/100 ml, you must immediately stop distributing the water; investigate the cause of the problem; take corrective actions; resample/test the water; and notify FDB Water Licensing Desk. You must not resume the distribution of water until the test shows that the water contains total coliforms of less than 2.2 MPN/100 ml.

- b. Test for volatile organic chemicals: You must test your water for quality if you change the water treatment process or replace major equipment such as reverse osmosis unit, water tank, water pump, activated carbon, etc. Maintain the original test result report, and send a photocopy of the report to your local FDB office. The testing laboratory may send a copy of the test report directly to the local FDB office on your behalf. The laboratory must clearly identify your firm name, address, and license number on the report. You can obtain the list of certified laboratories near your location by calling DHS' Environmental Laboratory Accreditation Program (ELAP) at (510) 540-2800 or by visiting the following ELAP website:
<http://www.dhs.ca.gov/ps/ls/elap/html/LablistStart.htm>

Collect four samples for your water, and send all samples to the testing laboratory (the testing laboratory may take the samples directly, or ask you to take the samples following its sample collection instruction). The laboratory will make a composite of the 4 samples and test for substances other than volatile organic chemicals (VOC's). As for VOC's, the laboratory will randomly select one of the four samples (each product) and test for VOC's.

- c. Record keeping: You must keep all records/test data for at least for 2 years pursuant to the Title 21, Code of Federal Regulations, Section 129.80 (h). Refer to this Section regarding the types of information to be kept.
- d. You must inform FDB when any changes are made in the design or construction of your water treatment system.

FOOD AND DRUG BRANCH OFFICES

FDB Food Safety Inspection Unit-Northern Region

100 Paseo de San Antonio, Room 304, San Jose, CA 95113
Telephone: (408)277-1832; Fax: (408) 277-1141

FDB Food Safety Inspection Unit-Southern Region

1449 West Temple Street, Room 224, Los Angeles, CA 90026
Telephone: (213) 580-5720; Fax: (213) 580-5750

(Revised 04/07/04)